

II. REMARKS

Formal Matters

Claims 1, 3, 5, 6, 13-15, 17-21, 33, 35, 36, and 38-48 are pending after entry of the amendments set forth herein.

Claims 1, 3, 5, 6, 13-15, 17-21, 33, 35, 36, and 38-43 were examined and were rejected.

Claims 44-48 are added. No new matter is added by new claims 44-48.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Withdrawn rejections

Applicants note with gratitude that, as discussed on page 2 of the Advisory Action, the previous rejection of claims 1, 3, 5, 13-15, 17-21, 33, 35, 36, and 38-43 under 35 U.S.C. § 112, first paragraph, “written description,” has been withdrawn.

Applicants note with gratitude that previous rejections, under 35 U.S.C. § 112, first paragraph, “enablement,” have been withdrawn; in particular, the rejections relating to: a) mammary gland tissue promoter; b) making of non-human mammals by nuclear transfer; and c) scope of PUFAs, have been withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3, 5, 13-15, 17-21, 33, 35, 36, and 38-43 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

The Advisory Action asserted that the claims are not enabled over the scope of any fatty acid desaturase. Applicants respectfully traverse the rejection.

The specification provides ample description for how to make and use a transgenic non-human mammal comprising a desaturase-encoding transgene. The specification provides sources for nucleotide sequences encoding various desaturase proteins, which nucleotide sequences were well known in the art as of the priority date of the instant patent application. Specification, paragraph 0066. The specification provides working examples of transgenic non-human mammals comprising a transgene encoding SCD. Using the ample guidance provided in the specification, together with the knowledge and skill level in

the art, those of ordinary skill in the art could make a transgenic non-human mammal comprising a transgene encoding any desaturase.

As of the September 17, 2002 priority date of the instant application, a large number of fatty acid desaturases were known and had been characterized enzymatically; and the nucleotide sequences encoding numerous such fatty acid desaturases were known. The instant specification provides the GenBank accession numbers of several nucleotide sequences encoding various fatty acid desaturases.

In the instant application, Stearoyl CoA desaturase (SCD) was chosen as a model fatty acid desaturase, and SCD transgenic mice and goats were generated and characterized. However, one could readily generate a transgenic non-human mammal, as claimed, where the transgenic non-human mammal includes a transgene encoding any of a variety of fatty acid desaturases. For example, if a fatty acid desaturase-encoding nucleotide sequence were under transcriptional control of a mammary gland-specific promoter, one would reasonably expect that such a transgenic non-human mammal would produce milk having a level of monounsaturated fatty acids (MUFA) that is higher than the level of MUFA in milk of a non-transgenic mammal of the same species. This is because the structures of a wide variety of fatty acid desaturases are known and are conserved.

The April 6, 2005 Office Action stated that the art teaches that the family of fatty acid desaturases is vast, and that an artisan cannot predict whether any fatty acid desaturase from any species of mammal would necessarily have the same enzymatic activity as it has in the original animal. However, claim 1 recites that a tissue of the transgenic non-human mammal comprises a level of MUFA that is at least 5% higher than the level of MUFA in the same tissue of a non-transgenic mammal of the same species. The specification provides ample description as to how to measure the level of MUFA in a tissue of a transgenic non-human mammal. All that would be required to determine whether a given fatty acid desaturase transgene, when expressed in a transgenic non-human mammal, resulted in a higher level of MUFA in a tissue of the mammal, would be to measure the level of MUFA in the transgenic mammal. The specification teaches how to accomplish such. Accordingly, the specification is enabling for the full scope of the claims.

As discussed in the Declaration of James Murray, provided as Exhibit 1 on December 1, 2005, those skilled in the art would find it reasonable to expect that the results that were observed, using SCD as model fatty acid desaturase, would be observed using other fatty acid desaturases as transgenes. This is because the structures of a wide variety of fatty acid desaturases are known and the functional sites (e.g., catalytic domains) are conserved. Furthermore, as discussed in the Declaration of James Murray, recent work has demonstrated the ability of fatty acid desaturase genes from various eukaryotic species to function in transgenic plants or animals.

The Advisory Action stated that Pereira et al. ((2003) Prostaglandin, Leukotrienes and Essential Fatty Acids 68:97-106; "Pereira") teach that some insects have delta12 desaturase activity, but many animals do not have this ability; and that an artisan cannot predict that one can take any transgene construct comprising any nucleic acid sequence encoding any desaturase, such as a delta12 desaturase from the cockroach, and predict that it would have activity in milk. However, Pereira actually supports the fact that the instant claims are enabled for the full scope of fatty acid desaturases, because Pereira discusses the fact that the structure of a wide variety of fatty acid desaturases are known and the functional sites (e.g., catalytic domains) are conserved.

Furthermore, as discussed in the Declaration of James Murray, the *Caenorhadbitis elegans* fat-1 (an omega 3 desaturase) and fat-2 (a delta-12 desaturase) coding regions produced functional desaturase protein when expressed in HC11 mouse mammary epithelial cells (Morimoto et al., *J. Dairy Sci.* 88:1142-1146, 2005). Morimoto reported that a yeast delta-12 desaturase was functional in a mammalian cell, again showing that those skilled in the art would find it reasonable to expect that the results that were observed, using SCD as model fatty acid desaturase, would be observed using other fatty acid desaturases as transgenes.

Applicants submit that the rejection of claims 1, 3, 5, 13-15, 17-21, 33, 35, 36, and 38-43 under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

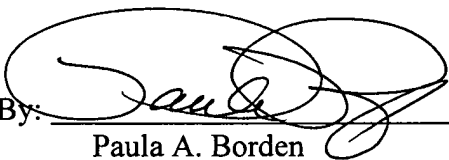
III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCDV-286.

Respectfully submitted,
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